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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,479	09/16/2005	Magdalene M. Moran	110313.138US2	6126
23483	7590	10/10/2007		
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			EXAMINER MONTANARI, DAVID A	
			ART UNIT 1632	PAPER NUMBER
			NOTIFICATION DATE 10/10/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com  
teresa.carvalho@wilmerhale.com  
tina.dougal@wilmerhale.com

## Office Action Summary

Application No.

10/523,479

Applicant(s)

MORAN ET AL.

Examiner

David Montanari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Furthermore, under PCT Rule 13.2 the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 15 drawn to an isolated nucleic acid consisting of SEQ ID NO:1.

Group II, claim(s) 2, drawn to an isolated nucleic acid consisting of SEQ ID NO:3.

Group III, claim(s) 3, drawn to an isolated nucleic acid consisting of multiple CatSper3 sequences selected from a-f.

Group IV, claim(s) 4, drawn to an isolated nucleic acid sequence consisting of multiple sequences from CatSper3 selected from a-k.

Group V, claim(s) 5, drawn to an isolated nucleic acid sequence encoding a polypeptide having at least 80% amino acid sequence with a CatSper3 sequence.

Group VI, claim(s) 6, drawn to an isolated nucleic acid encoding a polypeptide having CatSper3 activity in a cell.

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Group VII, claim(s) 7, drawn to an isolated nucleic acid regulatory sequences from SEQ ID NO: 5.

Group VIII, claim(s) 8-9, drawn to an isolated nucleic acid that hybridizes to at least a portion of SEQ ID NO's 1 or 3.

Group IX, claim(s) 10, drawn to a nucleic acid comprising a nucleotide sequence encoding a polypeptide having CatSper3 activity.

Group X, claim(s) 11, drawn to a nucleic acid comprising a nucleotide sequence having at least 80% amino acid identity with SEQ ID NO's 2 or 4.

Group XI, claim(s) 12-14, drawn to a kit for detecting a portion of CatSper3 nucleic acid.

Group XII, claim(s) 16-20, drawn to a vector comprising a genetic construct capable of expressing a nucleic acid.

Group XIII, claim(s) 21-25, drawn to a cell transformed with a nucleic acid.

Group XIV, claim(s) 26-28, drawn to a non-human transgenic animal.

Group XV, claim(s) 29, drawn to a substantially pure protein preparation comprising a CatSper3 polypeptide sequences.

Group XVI, claim(s) 30, drawn to a substantially pure protein preparation consisting of specific sequences selected from a-k.

Group XVII, claim(s) 31, drawn to a substantially pure protein preparation comprising a polypeptide having at least 80% amino acid sequence identity with a polypeptide from group consisting of a-d.

Group XVIII, claim(s) 32, drawn to a substantially pure protein preparation comprising a polypeptide having at least 80% amino acid sequence identity with a CatSper3 protein and capable of expressing CatSper3 in a cell.

Group XIX, claim(s) 33-40, drawn to a substantially pure antibody and a kit comprising said antibody.

Group XX, claim(s) 41-47, drawn to a method of identifying a potential modulator of CatSper3 activity in a cell.

Group XXI, claim(s) 48-49, drawn to drawn to a method of identifying a potential modulator of CatSper3 activity via binding assay.

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Group XXII, claim(s) 50-56 and 58-60, drawn to a method of decreasing fertility in a male subject using antisense.

Group XXIII, claim(s) 50-55 and 57-60, drawn to a method of decreasing fertility in a male subject using an antibody.

Group XXIV, claim(s) 61-67 and 69-71, drawn to the use of a compound which decreases CatSper3 activity wherein said compound comprises antisense.

Group XXV, claim(s) 61-66 and 68-71, drawn to the use of a compound which decreases CatSper3 activity wherein said compound comprises an antibody.

Group XXVI, claim(s) 72-74, drawn to a contraceptive preparation.

The inventions listed in Groups I-XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature linking groups I-XXVI appears to be that they all relate to a CatSper3.

However, Chan et al., 1997, Cation and anion channels in rat and human spermatozoa, Vol. 1323, pgs. 117-129 teach potassium and sodium cation channels isolated from rat and human sperm.

Therefore, the technical feature linking the inventions of groups I-XXVI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is SEQ ID NO:1.

The special technical feature of Group II is SEQ ID NO:3.

The special technical feature of Group III is multiple CatSper3 sequences selected from a-f.

The special technical feature of Group IV is multiple CatSper3 sequences selected from a-k.

The special technical feature of Group V is polypeptide having at least 80% amino acid sequence with a CatSper3 sequence.

The special technical feature of Group VI is CatSper3 activity in a cell.

The special technical feature of Group VII is SEQ ID NO: 5.

The special technical feature of Group VIII is isolated nucleic acid that hybridizes to at least a portion of SEQ ID NO's 1 or 3.

The special technical feature of Group IX is CatSper3 activity.

The special technical feature of Group X is SEQ ID NO's 2 or 4.

The special technical feature of Group XI is kit.

The special technical feature of Group XII is a vector.

The special technical feature of Group XIII is a cell.

The special technical feature of Group XIV is a non-human transgenic animal.

The special technical feature of Group XV is a protein.

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The special technical feature of Group XVI is a protein comprising sequences a-k.  
The special technical feature of Group XVII is a protein having least 80% amino acid sequence identity with a polypeptide from group consisting of a-d.  
The special technical feature of Group XVIII is expressing CatSper3 activity in a cell.  
The special technical feature of Group XIX is an antibody and kit.  
The special technical feature of Group XX is a modulator of CatSper3.  
The special technical feature of Group XXI is binding assay.  
The special technical feature of Group XXII is antisense.  
The special technical feature of Group XXIII is an antibody.  
The special technical feature of Group XXIV is use of antisense.  
The special technical feature of Group XXV is use of antibody.  
The special technical feature of Group XXVI is a contraceptive preparation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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David A. Montanari, Ph.D.

/Anne-Marie Falk/  
Anne-Marie Falk, Ph.D.  
Primary Examiner, Art Unit 1632